FILED

961451 MAR 13 1997

OFFICE OF THE CLERK

No. 96-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

COLLAGEN CORPORATION,
Cross-Petitioner,

v.

IRENE M. GREEN, *et al.*,
Cross-Respondents.

Conditional Cross-Petition for Writ of Certiorari to the Supreme Court of Pennsylvania

---

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

JOE W. REDDEN, JR.
Counsel of Record
KEITH A. JONES
BECK, REDDEN & SECREST, L.L.P.
1221 McKinney, Suite 4500
Houston, Texas 77010
(713) 951-3700

REEDER R. FOX
DUANE, MORRIS & HECKSCHER
One Liberty Place
Philadelphia, Pennsylvania 19103

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

11 pp

QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts a common law claim that the manufacturer of a medical device made fraudulent submissions to the Food and Drug Administration in connection with the agency's premarket approval process under 21 U.S.C. § 360e(c).*

---

* The parties below, in addition to cross-petitioner Collagen Corporation, were Irene M. Green, Martin Green, and Richard L. Dolsky. Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	iv
OPINIONS BELOW	1
JURISDICTION	2
STATUTE INVOLVED	2
STATEMENT	2
REASONS FOR GRANTING THE CROSS-PETITION	3
CONCLUSION	7

TABLE OF AUTHORITIES

Cases Page

King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) 4, 6
Mears v. Marshall, 137 Or. App. 390, 905 P.2d 1154 (1995), *vacated and remanded*, 324 Or. 130, 921 P.2d 966 (1996) 4, 6
Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996) 3, 4, 5
Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995) 4, 6
Mitchell v. Collagen Corp., 67 F.3d 1268 (7th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1996) 4, 6
Reeves v. AcroMed Corp., 44 F.3d 300 (5th Cir.), *cert. denied*, 115 S. Ct. 6

Statutes

21 U.S.C. § 360e(c) (Supp. 1995) ..... i, 2
21 U.S.C. § 360k(a) (Supp. 1995) ..... *passim*
28 U.S.C. § 1257 2

IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

No. 96-

COLLAGEN CORPORATION,
Cross-Petitioner,

v.

IRENE M. GREEN, *et al.*,
Cross-Respondents.

Conditional Cross-Petition for Writ of Certiorari to the Supreme Court of Pennsylvania

---

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

Collagen Corporation ("Collagen") respectfully cross-petitions for a writ of certiorari to review the judgment of the Supreme Court of Pennsylvania in this case. If the Court grants the petition in No. 96-1340, this cross-petition should be granted as well. If the Court denies that petition, this cross-petition should be denied.

OPINIONS BELOW

The opinion of the Pennsylvania Supreme Court is reported at 685 A.2d 110 (1996). Pet. App. 1-17 ("Pet. App." refers to the appendix to the petition in No. 96-1340). The opinions of the Pennsylvania Superior Court (Pet. App. 18-32) and the Court of Common Pleas of Montgomery County (Pet. App. 33-34) are not reported.

JURISDICTION

The judgment of the Supreme Court of Pennsylvania was entered on November 22, 1996. Pet. App. 15. Irene M. Green and Martin Green filed a petition for a writ of certiorari (No. 96-1340) on February 20, 1997, and the petition was docketed on that day. This conditional cross-petition is filed pursuant to Rule 12.5 of this Court. The Court's jurisdiction is invoked under 28 U.S.C. § 1257.

STATUTE INVOLVED

21 U.S.C. § 360k(a) in pertinent part provides:

> . . . no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

STATEMENT

The facts and proceedings below are discussed in full in Collagen's brief in response to the petition filed in No. 96-1340 ("Collagen Resp."). In summary, cross-respondents Irene M. Green and Martin Green sued Collagen on various tort law theories, claiming injury resulting from treatment with Zyderm®, a medical device manufactured by Collagen that has been found safe and effective and approved for marketing by the Food and Drug Administration ("FDA") pursuant to the statutory premarket approval ("PMA") process under 21 U.S.C. § 360e(c).

The Pennsylvania Supreme Court held that most of the Greens' claims are barred by the MDA preemption statute,

21 U.S.C. § 360k(a). Pet. App. 11-12, 14. The court ruled that two categories of claims, however, are not barred. First, the court held that the Greens could pursue their claim that Collagen had failed to conduct post-approval studies as required by the FDA. *Id.* at 14 & n.8. Collagen does not seek review of that ruling.

Second, the court held that the Greens are entitled to bring a laundry list of claims that allege, "in essence, that [Collagen] fraudulently completed the premarket approval process." Pet. App. 12-13 n.7. This ruling, which permits litigation of common law claims alleging that a manufacturer defrauded the FDA in the course of the PMA process, is the subject of this conditional cross-petition.

The Green's claim that Collagen defrauded the FDA is factually baseless. In 1991, ten years after granting Zyderm premarket approval, the FDA itself, in the face of similar accusations, carefully reviewed the record and reconfirmed its finding that Zyderm is safe and effective. *See* Collagen Resp. 4. But the point of this cross-petition is that the MDA preemption statute does not authorize or permit the comprehensive judicial intrusion into the agency's PMA process that litigation of such claims would entail.

REASONS FOR GRANTING THE CROSS-PETITION

As Collagen explained in its response to the petition in No. 96-1340, this Court should grant certiorari there to determine the application of the MDA preemption statute to cases involving medical devices that the FDA has found to be safe and effective and has approved for marketing pursuant to the PMA process. If that petition is granted, this cross-petition should be granted as well. Cases like this, involving tort claims with respect to medical devices that have "run[] the gauntlet of the PMA process," *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2254 (1996), commonly encompass a claim that the manufacturer de-

frauded the FDA during the course of that process. *See, e.g., Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2576 (1996); *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Mears v. Marshall*, 130 Or. App. 390, 905 P.2d 1154 (1995), *vacated and remanded*, 324 Or. 130, 921 P.2d 966 (1996). In determining the proper scope of MDA preemption, the Court should consider the application of the statute to these frequently asserted claims of "fraud on the FDA."

The court below reasoned that "[s]uch claims are cognizable for they mirror FDA prohibitions against fraud." Pet. App. 12-13 n.7. The court did not identify any specific regulation actually setting forth such a prohibition, but Collagen has no doubt that the regulations governing the PMA process either explicitly or implicitly forbid fraudulent submissions. That fact, however, should not insulate common law claims of "fraud on the FDA" from preemption.

Although the court below did not say so, it may have believed that its ruling on this issue was dictated by *Lohr*. If so, the court was misreading this Court's decision. In *Lohr*, this Court held that 21 U.S.C. § 360k(a) does not bar state law tort claims alleging that a medical device has been manufactured and distributed in violation of FDA regulations. *Lohr*, 116 S. Ct. at 2255-56. The Court reasoned that the state requirements embodied in such claims are not "different from, or in addition to, any [federal] requirement," within the meaning of the MDA preemption statute. But claims of "fraud on the FDA" are of a wholly different species.

The Court's decision in *Lohr* means, for example, that if a manufacturer negligently fails to comply with the FDA's requirements relating to quality controls or label-

ing, state law can, in effect, enforce those requirements. This is, at least in theory, a simple matter: the FDA's requirements with respect to quality controls or labeling are taken as a given; the court determines as a factual matter whether those requirements were met; if they were not met, and the failure to meet them caused injury, the court enforces the requirements through an award of damages. Nothing in this process impairs the integrity of the federal regulatory scheme. To the contrary, such a process, if conducted with a proper understanding of the actual federal requirements, could serve to support and reinforce FDA's informed judgment concerning how the particular medical device should be manufactured and distributed.

Claims of "fraud on the FDA" are designed to have, and if recognized will have, precisely the opposite result, The thrust of such claims is that (1) had the FDA known the "true" facts, either it would not have found the medical device to be safe and effective or, in approving the device for marketing, it would have imposed different requirements with respect to such matters as manufacturing or labeling, and (2) therefore the court itself, or the jury, should replace the FDA's actual determinations either with a determination that the device in fact is not safe and effective or by imposing different or additional requirements that the manufacturer in fact did not meet. Such a process supplants the FDA and destroys the integrity of the federal regulatory scheme. Nothing could be more contrary to both the letter and the spirit of 21 U.S.C. § 360k(a).

It therefore is not surprising that every court that specifically addressed this issue prior to *Lohr* held that the FDA preemption statute bars tort claims alleging "fraud on the FDA." As the Third Circuit explained, such claims

> encourage the district court to review the PMA application [the manufacturer] submitted to the FDA. This inquiry could ultimately require that a court determine whether the information [the manufac-

> turer] submitted was truthful, whether it was complete, whether FDA procedures sufficed to avoid a material misrepresentation, and whether the FDA should have or would have approved the device despite the misrepresentations. In sum, this claim requires a court, applying state law, to perform the same functions initially entrusted to the FDA.
>
> Section 360k does not permit such a searching state inquiry into the inner workings of FDA procedures. Congress allocated the FDA responsibility to design and manage a process which would result in approval of the safest and most effective medical devices possible. Congress also assigned the FDA the responsibility to approve or disapprove of applications to market medical devices. Under § 360k, states may not impose different requirements and thereby reach a different conclusion than the FDA.

Michael, 46 F.3d at 1329. The First Circuit similarly noted:

> Surely, where the FDA was authorized to render the expert decision on [the manufacturer's] use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions. Further, if the court erred, and incorrectly posited the effect on the FDA's use and labeling decision, this would impose a state requirement "which is different from, or in addition to, any requirement applicable . . . to the device."

King, 983 F.2d at 1140 (Aldrich and Campbell, JJ., concurring); *see also, e.g., Mitchell,* 67 F.3d at 1284; *Reeves v. AcroMed Corp.,* 44 F.3d 300, 306 (5th Cir.), *cert. denied,* 115 S. Ct. 2251 (1995); *Mears,* 137 Or. App. at 406-07, 905 P.2d at 1166-67.

If this Court grants review in this case, it should correct the lower court's error in allowing the Greens to claim "fraud on the FDA." A common law judge and jury cannot be allowed to displace the FDA and its

statutory PMA process by substituting their own views concerning whether and how a medical device is to be manufactured and marketed. The court below glossed over this important concern, which lies at the very heart of the MDA preemption statute.

CONCLUSION

If the petition for a writ of certiorari is granted in No. 96-1340, this cross-petition also should be granted. If that petition is denied, the cross-petition also should be denied.

Respectfully submitted,

JOE W. REDDEN, JR.
Counsel of Record
KEITH A. JONES
BECK, REDDEN & SECREST, L.L.P.
1221 McKinney, Suite 4500
Houston, Texas 77010
(713) 951-3700

REEDER R. FOX
DUANE, MORRIS & HECKSCHER
One Liberty Place
Philadelphia, Pennsylvania 19103

No. 96-1451

Supreme Court, U.S.
FILED
APR 11 1997
CLERK

In The

Supreme Court of the United States

October Term, 1996

COLLAGEN CORPORATION,

Cross-Petitioner,

vs.

IRENE GREEN and MARTIN GREEN,

Cross-Respondents.

On Conditional Cross-Petition for Writ of Certiorari to the Supreme Court of Pennsylvania

BRIEF OF IRENE AND MARTIN GREEN IN RESPONSE TO CONDITIONAL CROSS-PETITION

LINDLEY M. COWPERTHWAIT, JR.
HIGH, SWARTZ, ROBERTS
& SEIDEL
40 East Airy Street
Norristown, PA 19401
(610) 275-0700

MICHAEL M. ESSMYER
Counsel of Record
ESSMYER, TRITICO
& CLARY, L.L.P.
4300 Scotland
Houston, TX 77007
(713) 868-1111

CLINARD J. HANBY
25025 I-45 North
Suite 525
The Woodlands, TX 77380
(713) 364-6930

Attorneys for Cross-Respondents

70946 (800) 3 APPEAL • (800) 5 APPEAL • (800) BRIEF 21 Lutz Appellate Services, Inc.

QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts state tort law claims against a manufacturer and treating physician to recover for injuries caused by a PMA-approved Class III medical device.

STATEMENT OF THE CASE

Cross-respondents Irene Green and Martin Green respectfully request that this Court deny the conditional cross-petition for writ of certiorari filed by cross-petitioner Collagen Corporation, which seeks partial review of the Pennsylvania Supreme Court's opinion in this case. The Pennsylvania Supreme Court's opinion is reported at 685 A.2d 110 (1996).

In its conditional cross-petition, cross-petitioner Collagen Corporation specifically relies on the facts and proceedings as reported in its brief in response to the petition filed by Irene and Martin Green in No. 96-1340. The facts set out by cross-petitioner Collagen Corporation in its response ("Coll. Resp.") are incorrect, misleading and/or incomplete in the following respects.

1. Any assertion by Collagen Corporation that its Class III device Zyderm was approved under the FDA's regulations appearing at 21 C.F.R. § 814.20, *et seq.*, is incorrect. The PMA for Zyderm was approved in 1981 (Coll. Resp. 4). C.F.R. regulations for pre-market applications were not promulgated by the FDA until 1986, five years after approval of the Zyderm PMA.

2. Cross-petitioner Collagen Corporation's assertion that it cannot modify Zyderm's packaging or warnings without prior FDA approval is false. Cross-petitioner only *partially* cited the FDA's "conditions of approval" for Zyderm, stating that cross-petitioner cannot make any packaging or labeling changes without FDA approval. (Coll. Resp. 4). In truth, those portions of the conditions of approval *omitted* by cross-petitioner in its Brief unequivocally allow cross-petitioner to make packaging and labeling warning modifications *without* prior FDA approval where such changes would enhance safety and effectiveness.

Collagen Corporation's hands were not tied in the event it wanted to warn consumers and physicians of autoimmune risks and injuries regarding Zyderm.

3. The FDA had *not* in 1991 "reviewed Zyderm's record and reconfirmed in its initial finding of safety and effectiveness," as alleged by cross-petitioner (Coll. Resp. 4; Cross-Pet. 3). Rather, in response to a congressional investigation involving Collagen Corporation, the FDA re-reviewed the *original* 1980 PMA materials submitted by cross-petitioner for Zyderm, and determined that under 1980 standards, the PMA had been properly approved. Such a finding does not in any way act to rehabilitate what Collagen Corporation has done since, nor absolve Collagen of any fraud claims.

REASONS WHY THE CONDITIONAL CROSS-PETITION SHOULD BE DENIED

SECTION 360k(a) SHOULD NOT INSULATE DEVICE MANUFACTURERS FROM CLAIMS BASED IN THE FILING AND PURSUING OF FRAUDULENT PMAs FOR CLASS III MEDICAL DEVICES.

As the sole basis for its conditional cross-petition, Collagen Corporation argues that, above all, Section 360k(a) of the MDA should insulate it and other device manufacturers from fraud in the submission of PMAs. Stated differently, Collagen Corporation asks this Court to rule that a Class III device manufacturer should not be liable to persons injured by the device, where the device has been allowed on the market through the manufacturer's fraud on the FDA.

In fashioning this argument, Collagen admits that implicit in the MDA regulations is the requirement that device manufacturers not perpetrate fraud in PMA device submissions.

Collagen further admits that *Lohr* clearly holds that § 360k(a) allows state law claims which allege that a device has been manufactured or distributed in violation of FDA regulations. Despite this clarity of application, Collagen argues that fraud claims should nonetheless be preempted, as to allow fraud claims to proceed against it would somehow bring crashing down the entire FDA regulatory system.

Primarily, cross-petitioner Collagen Corporation contends that fraud claims would "impair the integrity of the federal regulatory scheme" (Cross-pet. 5), specifically by allowing a trial court to find that had the FDA known the "true" facts, it would not have granted marketing approval, or may have imposed different conditions of approval. This, states Collagen, impermissibly allows the trial court to substitute its finding for that of the FDA and hold that the device is not safe or effective.

This analogy, however, does not establish a "special" set of circumstances applicable only to fraud claims. By substituting *Lohr's* allowance of claims for improper manufacturing and distribution, *any* claim grounded on violation of FDA regulations, whether based in fraud or not, would be allowed under *Lohr*.

Moreover, Collagen's argument misses its mark — the question of fraud (as with that of violation of FDA requirements) focuses not on an invasive analysis of the FDA's actions, but on an inquiry into the *manufacturer's* actions under the circumstances. Cross-respondents' allegations that cross-petitioner Collagen Corporation acted fraudulently regarding its Zyderm device would not allow trial courts to substitute "their own views concerning whether and how a medical device is to be manufactured and marketed" (Cross-pet. 7). Rather, a finding of fraud is a finding of fraud; it does not undo the FDA's decisions, and does not create substitute administrative proceedings. It would not, contrary to Collagen's claim,

"requir[e] a court, applying state law, to perform the same functions initially entrusted to the FDA" (Cross-pet. 6).

Indeed, if anything could bring the FDA regulatory scheme crashing down and destroy the integrity of the entire process, it would be the past, present and future continued use of fraud by device manufacturers such as Collagen Corporation in the submission of medical device PMAs. The PMA scheme *relies* on honesty and complete disclosure by device manufacturers, as the FDA itself does not "second guess" the integrity of the submitted data. By allowing injured parties to pursue fraud claims, the MDA and FDA scheme would not be destroyed, but to the contrary (borrowing from Collagen Corporation's own language),

> such a process, if conducted with a proper understanding of the actual federal requirements, could serve to support and reinforce FDA's informed judgment concerning how the particular medical device should be manufactured and distributed.

(Cross-pet. 5).

In making this statement above (*Id.*), Collagen Corporation concedes that certain state tort laws could enhance the FDA administrative procedures regarding medical devices. If anything, fraud-based claims would greatly enhance FDA's procedures regarding medical devices — fraudulent submissions brought to light through litigation could be utilized by the FDA for its own administrative purposes. Collagen's specious protestations notwithstanding, there is no excuse, no justification, for allowing a device manufacturer to hide behind fraud to the detriment of consumers and the public at large.

This Court's ruling in *Lohr v. Medtronic* controls this issue. Fraud-based claims, in raising violations of the regulation requiring honesty and prohibition against deceit and falsification implicit within the MDA, would seek enforcement of the MDA regulations, and are expressly allowed by *Lohr.*

CONCLUSION

If the petition for a writ of certiorari is granted in No. 96-1340, *Green v. Collagen Corporation, et al.*, Collagen Corporation's conditional cross-petition should be denied.

Respectfully submitted,

MICHAEL M. ESSMYER
Counsel of Record
ESSMYER, TRITICO
& CLARY, L.L.P.
4300 Scotland
Houston, TX 77007
(713) 868-1111

CLINARD J. HANBY
25025 I-45 North
Suite 525
The Woodlands, TX 77380
(713) 364-6930

LINDLEY M.
COWPERTHWAIT, JR.
HIGH, SWARTZ, ROBERTS
& SEIDEL
40 East Airy Street
Norristown, PA 19401
(610) 275-0700

Attorneys for Cross-Respondents